

Remarks

Claims 19-24 are canceled without prejudice. Claim 18 has been amended to recite the limitations found in claim 21. No new matter is believed added. Entry of these claims is respectfully requested. Reconsideration and further examination are respectfully requested.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 22-24 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses this rejection.

Claims 22-24 have been canceled. Applicant has canceled these claims solely to expedite prosecution and does not acquiesce to the rejection for reasons of record. As the rejected claims have been canceled, applicant asserts that this rejection is moot and respectfully requests its withdrawal.

Claims 19-20 and 22-24 are rejected under § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses this rejection.

Claims 19-20 and 22-24 have been canceled. Applicant has canceled these claims solely to expedite prosecution and does not acquiesce to the rejection for reasons of record. As the rejected claims have been canceled, applicant asserts that this rejection is moot and respectfully requests its withdrawal.

Rejections under 35 U.S.C. § 102(b)

A. Claims 18 and 21 are allegedly anticipated by Luo *et al.* The Office Action states that Luo *et al.* describes methods where galanin is administered to treat spinal cord hyperexcitability following sciatic nerve section, which is peripheral nerve damage. Applicant respectfully traverses this rejection.

Claim 21 has been canceled. Claim 18 has been amended to include the limitation that the nerve damage is peripheral nerve damage. In response to the rejection as it pertains to newly amended claim 18, applicant respectfully traverses the rejection. Luo *et al.* demonstrates that galanin inhibits spinal cord electrical hyper-excitability following nerve section (axotomy). As Luo *et al.* point out in their discussion, spinal cord excitability, especially after injury, is directly related to the development of chronic pain states, and the blockade of electrical discharge reduces neuropathic behavior. Luo *et al.* deals exclusively with neuropathic pain behavior. Claim 18, as amended, is restricted to peripheral nerve damage. Peripheral nerve damage, as claimed in the present invention, is by no means synonymous with chronic neuropathic pain, as taught by Luo *et al.* Thus, the fact that galanin may be a pain treatment is irrelevant to the instant invention. Therefore, the teachings of Luo *et al.* do not teach or suggest the method of claim 18.

B. Claim 18 is allegedly anticipated by Liu *et al.* The Office Action states that the abstract of Liu *et al.* describes methods where galanin is administered to treat traumatic brain injury, and the administration of galanin lessens sensory motor deficits following brain injury, indicating its effectiveness. Applicant respectfully traverses this rejection.

Claim 18 has been amended to include the limitation that the nerve damage is peripheral nerve damage. Liu *et al.* deals exclusively with injury to the brain, i.e., the central nervous system (CNS). Claim 18, as amended, is restricted to the peripheral nervous system (PNS). As discussed above, peripheral neurons regenerate after injury whilst neurons from the CNS do not.

Furthermore, the mechanisms and molecular cascades that regulate these distinct processes are very different. Thus, the Liu *et al.* reference does not describe damage to the PNS. The only effects they noted after the central administration of galanin were short term, relating to the neuromodulatory role played by galanin (i.e., short term administration of galanin alters the transient release of excitatory amino-acids such as glutamate) on motor function such as beam balance and rotarod. Therefore, Liu *et al.* does not teach or suggest a method of treatment of peripheral nerve damage in a subject using galanin.

Rejection under 35 U.S.C. § 103(a)

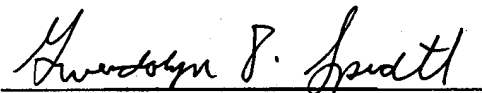
Claims 18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo *et al.* in view of Kaplan. According to the Examiner, the teachings of Luo *et al.* are set out above. Luo *et al.* does not teach methods using galanin agonists that are not galanin. Kaplan teaches the use of galanin agonists which are N-terminal fragments of galanin. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to use galanin fragments in lieu of galanin because galanin is a peptide. Applicant respectfully traverses this rejection.

Claims 21-22 have been canceled. Claim 18 has been amended to include the limitation that the nerve damage is peripheral nerve damage. The combination of Luo *et al.* and Kaplan fails to suggest the invention of amended claim 18. The Luo *et al.* reference relates to pain rather than the treatment of peripheral nerve damage. Thus, Luo *et al.* does not provide any teaching or suggestion regarding the treatment of peripheral nerve damage. The teachings of Kaplan does not compensate for this deficit, as Kaplan does not teach the use of galanin to treat peripheral nerve damage. Therefore, these two references, when combined, do not render the present invention obvious.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application are believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

No fees are believed due, however, the Commissioner is hereby authorized to charge any additional fees due or credit any overpayment to Deposit Account No. 14-0629.

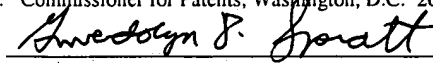
Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date shown below.



Gwendolyn D. Spratt

2-6-03

Date

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel claims 19-24 without prejudice.

18. (Amended) A method for the treatment of peripheral nerve damage in a subject in need of such treatment, the method comprising the step of administering to the subject an amount of a galanin agonist effective to treat peripheral nerve damage.